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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,366	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,23-27 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,23-27 and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 3/24/06
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 31, 2006 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11, 23-27, and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claim 1, lines 13-17, the phrase "said biosensor enabling the shrunk cell components to permeate together with the liquid specimen into said reaction layer in a mixed state for analysis to occur" is vague and confusing. The phrase seems to suggest that the cell components are distinct from the liquid specimen. However, the specification does not provide disclosure for a sample that includes two different samples applied simultaneously, wherein one of the samples consists of cell components and the other a liquid specimen. It is therefore unclear whether Applicants' intended to claim two distinct samples or one sample that includes cell components.

5. Claim 23 recites the limitation "the reaction" in line 11. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 23 recites the limitation "the blood specimen" in line 15. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 23 recites the limitation "the blood components" in line 17. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 23 recites the limitation "the cell components" in line 18. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 23 recites the limitation "which are shrunk by the dissolved cell shrinkage reagent" in line 19. There is insufficient antecedent basis for this limitation in the claim. The limitations prior to the instant limitation do not disclose the step of shrinking cell components.

10. In claim 23, lines 19-20 and 26-28, the phrases "mixed with the liquid specimen" and "the shrunk cell components and the liquid specimen are permeated into the reaction layer in a state where each of the shrunk cell components and the liquid specimen are mixed" are vague and confusing. The phrase seems to suggest that the cell components are distinct from the liquid specimen. However, the instant claim does

not disclose the addition of multiple solutions, and it seems as if the term "blood specimen", from which the "cell components" are derived, and the term "liquid specimen" are used interchangeably. It is therefore unclear whether there is one sample or multiple samples, and how the "cell components" are related to the "liquid specimen".

11. In claims 31 and 34, the phrase "0.1 ~ 5.0M" is vague and indefinite. It is unclear whether the instant phrase is a range.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4, 7-9, 11, 23-25, 31, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (US 5,607,863).

Chandler reference teaches a device (i.e. biosensor) comprising a first opposable component 462 (i.e. carrier) with a first end 476, and second end 478, and a detection zone 484 containing an immobilized specific binding partner to an analyte (i.e. reaction layer), wherein the first end 476 is in contact with a sample preparation zone 488 that can function as a sample addition zone (i.e. carrier on at least a part of an area), and

wherein the device also includes an applicator 498 containing a labeled specific binding partner to the analyte in a resolubilizable form (i.e. reagent holding part; carrier ranges from a specimen addition part to a reagent holding part). See column 38, lines 31-67; column 39, lines 5-7; and Figures 12A-B. Furthermore, Chandler also teaches that the sample preparation zone includes sodium nitrite (i.e. cell shrinkage reagent; inorganic acid) to lyse cells and extract analytes therein, wherein the sodium nitrite is present in dried form on the sample preparation zone (i.e. cell shrinkage reagent is dried). See column 21, line 60 to column 20, line 7.

With respect to claims 2 and 24, Chandler teaches blood samples (i.e. whole blood). See column 57, lines 1-2.

With respect to claim 3, Chandler teaches samples with bacteria (i.e. solution including bacteria). See column 22, line 1.

With respect to claims 4 and 25, since Chandler teaches that the sample is applied to dried sodium nitrite prior to the addition of acetic acid, which would necessarily produce cell shrinking due to the exclusive combination of the sodium nitrite and sample. See column 22, lines 4-7.

With respect to claims 7-9, section 2113 of the MPEP is particularly relevant:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding

the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Since the claims are directed towards a product (i.e. cell shrinkage reagent) and not a process, the claims are considered to be product-by-process claims for purposes of determining patentability. The patentable subject matter of the instant claims is therefore a dried cell shrinkage reagent. Since Chandler teaches that the sodium nitrite is in a dried form, as disclosed above, the instant claims are anticipated.

With respect to claims 11 and 33, Chandler teaches that the chromatographic medium is a strip composed of nitrocellulose, nylon, rayon, cellulose, paper, or silica (i.e. dry analytical element). See column 16, lines 21-38.

With respect to claim 23, Chandler teaches the step of applying sample to the sample preparation zone, which contains the sodium nitrite reagent in dried form (i.e. dissolving the cell shrinkage reagent by the blood specimen added to the specimen addition part). See column 21, line 60 to column 22, line 7. Further with respect to claim 23, Chandler teaches that the sample is allowed to migrate through the chromatographic medium 474 into the detection zone (i.e. chromatographically permeating the blood components including shrunk cells; shrunk cell components and the liquid specimen are permeated into the reaction layer in a state where each of the shrunk cell components and the liquid specimen are mixed) and an aqueous liquid is added to the applicator 498 housing dried labeling reagents to resolubilize the reagents to form a ternary complex with the analyte at the detection zone (i.e. marking the

analyte in the liquid specimen with the reagent which has been held in the reagent holding part; analysis of the analyte in the liquid specimen is performed in said reaction layer). See column 39, lines 5-24.

With respect to claims 31 and 34, Chandler teaches a 2M sodium nitrite concentration (i.e. concentration of the cell shrinkage reagent is 0.1 ~ 5.0M). See column 56, line 7.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 5-6 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 5,607,863) as applied to claims 1 and 23 above, and further in view of Fruitstone et al (US 4,259,207) and Killeen et al (US 5,166,051).

Chandler reference has been disclosed above, but fail to teach that the cell shrinkage reagent is an amino acid or a saccharide.

Fruitstone et al teach that solutes such as amino acids and sugars may be employed to control osmolality, in order for cells to become crenated if the osmolality of the solution is too high. See column 3, lines 3-20.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Chandler, with solutes such as amino acids and sugars that may be employed to control osmolality, as taught by Fruitstone et al, since it is well known in the art that a crenating agent may be any constituent or composition which effectively reduce the volume of water in blood cells. See Killeen et al, column 5, lines 48-51.

The Courts have ruled that art-recognized equivalence between embodiments provides a strong case of obviousness in substituting one material for another. See MPEP 2144.06:

> In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.).

In regards to the instant application, the specification teaches that the inorganic salt, amino acid, and saccharide can be applied in lieu of one another and does not set forth a reason for choosing one specific embodiment over another. For example, on page 21, 2nd paragraph, Applicants state "The cell shrinkage reagent held by the shrinkage reagent holding part 8 is for example inorganic salt, amino acid, or saccharide." Nowhere in the specification is there disclosure that either the inorganic salt, amino acid, or saccharide are preferred in certain situations. The specification therefore indicates that the different inorganic salt, amino acid, and saccharide compounds as disclosed are not specific for any particular purpose, but can be used interchangeably.

Because Killeen et al reference teaches that a crenating agent may be any constituent or composition which effectively reduces the volume of water in blood cells, and Applicants have not provided evidence indicating why inorganic salt, amino acid, or saccharide cannot be considered art-recognized equivalents, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the amino acid and sugars, as taught by Fruitstone et al, for the sodium nitrite of Chandler. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in substituting the amino acid and sugars of Fruitstone et al in the method of Chandler, since Chandler teaches that any reagent can be applied to the sample preparation zone, depending on the type of assay being performed. See column 21, lines 60-64.

18. Claims 10 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US 5,607,863) in view of Killeen et al (US 5,166,051).

Chandler reference has been disclosed above, but fails to teach that the applied device configuration is a one-step immunochromatographic test strip.

Killeen et al reference teaches a diagnostic test strip that requires only the addition of a test fluid containing target analyte applied to the matrix, and no additional active steps to perform the assay. See column 9, lines 5-17.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus and method of Chandler with a diagnostic test strip that requires only the addition of a test fluid containing target analyte applied to the

matrix, and no additional active steps to perform the assay, as taught by Killen et al, since Chandler discloses that one-component assay devices eliminate the need to prepare a separate solution of sample and a labeled specific partner, which provides a more efficient way of performing an assay. See column 19, lines 40-47.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
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